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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1615	10

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,241		
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 July 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) 21 and 23 is/are withdrawn from consideration.

5) Claim(s) 27 is/are allowed.

6) Claim(s) 1-17, 19, 20, 22 and 24-26 is/are rejected.

7) Claim(s) 18 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3-5</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Examiner acknowledges receipt of preliminary amendment A filed 12/20/01, IDS filed 1/24/02, 02/13/02 and 03/25/02, election filed 04/11/03 and 07/21/03.

Election Requirement

The office action mailed on 07/21/03 was a requirement for the applicants to elect a specific brain tumor for prosecution on the merits and for applicants to state on the record that all the claimed brain tumors are obvious variants if applicants object/traverse the election requirement. It is also noted that upon the allowance of a generic claim applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all limitations of an allowed generic claim as provided by 37 CFR 1.141.

Applicants elected with traverse glioblastomas as the specific tumor and 5-fluorouracil (5-FU) anticancer agent; and argue that the instant invention is directed to “the treatment of inoperable tumors using biodegradable microspheres which release an anticancer agent by stereotactic injection.” However, glioblastomas and osseous tumor appear not to be the same. Examination is also extended to carboplatin anticancer agent. Thus examination is directed to claims 1-20, 22 and 24-27 as identified by applicants to read on the elected species. Claims 21 and 23 are withdrawn from examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 contains the trademark/trade name POLYSORBATE. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-7, 9-13, 14, 15, 17, 19, 20, 22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emerich et al. ("Injectable Chemotherapeutic Microspheres and Glioma II: Enhance Survival Following Implantation Into Deep Inoperable Tumors," *Pharmaceutical Research*, Vol. 17, no. 7, 2000, pages 776-781).

Emerich discloses chemotherapeutic implantable, biodegradable polymer comprises carboplatin or BCNU for treating glioma and the carboplatin-loaded microspheres are injected into the center of the tumor (abstract). The microspheres are stereotactically injected into the tumors and the implantable biodegradable carboplatin loaded microsphere composition contains 0.9% saline, 0.1% TWEEN and 3% carboxymethylcellulose and the composition has a low viscosity (page 777). The biodegradable polymer inherently delays the release of the carboplatin. Administration of the carboplatin-loaded microsphere into the tumor would inherently maintain an effective concentration for a period of time including up to at least three weeks. In the absence of a showing of criticality, amounts of viscosity modifier and isotonicity agent and mg amount of biodegradable microspheres do not patentably distinguish the instant claims over the prior art that teaches the respective composition for treating glioma.

However, while Emerich discloses treating glioma with the carboplatin-loaded microsphere, Emerich differs from the instant claims by not teaching administration of the carboplatin-loaded microsphere into a human tumor. Emerich uses a rat model to study release of the carboplatin into the tumor and studies are generally done in small animal model before clinical trials and use in the bigger animal model such as the human. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to test an optimized composition of the prior art in the rat small animal model. One having ordinary skill in the art would have been motivated to stereotactically administer the optimized composition of the prior art into a human suffering from glioma with the expectation that carboplatin loaded microsphere would release the anticancer agent carboplatin in the tumor or temporal area for treating the glioma that affects humans.

5. Claims 1-9, 16, 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boisdstron-Celle et al. ("Preparation and Characterization of 5-Fluorouracil-loaded microparticles as Biodegradable Anticancer Drug Carriers," *J. Pharm. Pharmacol.* 1999, 47: 108-114).

Boisdstron-Celle discloses a controlled release device comprising biodegradable microspheres that comprise PLGA (50% lactic acid and 50% glycolic acid) polymer and 5-fluorouracil in stable emulsion for stereotactic injection and 5-fluorouracil (5-FU) is used to treat common human glioblastoma, most common human glioma (abstract and pages 108-114).

Boisdstron-Celle differs from the instant claims by failing to teach administration of the 5-FU loaded microsphere into a human tumor. Boisdstron-Celle uses in vitro analysis to test the release pattern of 5-FU loaded PLAGA microspheres. However, the aim of the study is to be able to stereotactically implant the 5-FU loaded microspheres in the brain to treat brain tumors such as glioblastoma, which is the most common human malignant glioma.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to test an optimized composition of the prior art in the in vitro model. One having ordinary skill in the art would have been motivated to stereotactically administer the optimized composition of the prior art into a human suffering from glioma with the expectation that 5-FU loaded microsphere would release the anticancer agent 5-FU in the tumor or tumoral area for treating glioblastoma.

6. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and

any intervening claims. The prior art does not teach administering anticancer loaded microsphere stereotactically into a human tumor followed by radiotherapy.

7. Claim 27 is allowable because the prior art does not teach a radiotherapy step of treatment following the stereotactic injection of anticancer loaded microspheres.

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.


Blessing Fubara
Patent Examiner
Tech. Center 1600